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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,568	02/18/2004	Edouard Koullick	539.5005.1	9297

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INTELLECTUAL PROPERTY GROUP
FREDRIKSON & BYRON, P.A.
200 SOUTH SIXTH STREET
SUITE 4000
MINNEAPOLIS, MN 55402

EXAMINER	
DEAK, LESLIE R	
ART UNIT	**PAPER NUMBER**
3761	

MAIL DATE	DELIVERY MODE
05/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/781,568	KOULLICK ET AL.	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,16-28,30-45,48-63,66 and 67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,16-28,30-45, 48-63,66,67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 19 March 2007 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 3, 6, 7, 11-13, 1618, 20, 23, 24, 28, 30-32, 34, 37, 38, 42-45, 48-50, 52, 55, 56, 60-63, 66, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 7,008,397 to Tweden in view of US 6,110,155 to Baudino, further in view of US 6,656,506 to Wu et al.

In the specification and figures, Tweden discloses the device substantially as claimed by applicant. With regard to claims 1, 18, 32, and 50, Tweden discloses a medical shunt in the shape of a hollow cylinder 20, forming a conduit 12 therein (see column 3, lines 60-67). The conduit has open ends 28, 30 that receive and discharge

body fluids (see column 4, lines 1-9). The shunt may comprise occlusion-resistant materials deployed in a delivery agent (such as a knitted cloth) that resist occlusion of the shunt (see column 1, lines 43-54, column 17, lines 50-60). (With specific regard to claims 32 and 50, see columns 15-17 for Tweden's disclosure of preparing or making the disclosed shunt, column 18 for Tweden's disclosed method of inhibiting occlusion by implanting the shunt and allowing the drugs to elute from the shunt.)

Tweden fails to disclose that the hunt comprises a plurality of apertures at the proximal end of the shunt or that the occlusion-resistant materials may be located on the internal surface of the tube. However, Baudino discloses a catheter comprising a conduit 14 with a plurality of apertures 32 at the distal end to improve fluid flow between the lumen 20 and the outside of the catheter (see FIG 2, column 3, lines 20-30). Furthermore, Baudino discloses that the catheter 14 may comprise a medicament that is dispersed throughout the polymeric catheter, allowing the medicament to diffuse into the patient from the interior and exterior of the catheter, preventing inflammation and blockage both inside and outside the catheter (see column 3, line 45 to column 4 line 7). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the shunt disclosed by Tweden with proximal apertures and medicaments on the interior of the shunt, as disclosed by Baudino, in order to improve fluid flow and prevent inflammation, as taught by Baudino.

Tweden and Baudino fail to disclose that the occlusion resistant materials are distributed in agent delivery devices comprising spheres, plugs, seeds, rods, or combinations thereof. Wu discloses an implantable medical device that incorporates

polymer-based drug eluting microparticles of various shapes (including spheres) in order to allow site-specific treatment within various portions of the implantable device (see column 2, lines 25-65, column 3, lines 29-31, 39-41, column 4, lines 20-25, 64-67, column 5, lines 10-30). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add drug eluting microspheres as disclosed by Wu to the drug eluting shunt suggested by the prior art, in order to provide site-specific treatment within various portions of the implantable device, as taught by Wu.

With regard to claims 3, 20, 34, and 52, Tweden discloses that the shunt may be made of a low-density polyethylene (see column 4, lines 50-55).

With regard to claims 6, 23, 37, and 55, Tweden discloses that the shunt may incorporate anticoagulants (see column 7, lines 39-40).

With regard to claim 7, 24, 38, and 56, Tweden discloses that the shunt may incorporate compounds containing silver (see column 8, lines 39-40).

With regard to claims 11-13, 16, 30, 42-45, 48, 60-63, and 66, Tweden discloses that the drugs incorporated as a part of the shunt may cover the entire shunt or portions thereof (see column 18, lines 35-38). Tweden's disclosure that a therapeutic agent is in "at least a partial covering" relationship to at least a first portion of the shunt indicates that the therapeutic agent may uniformly cover the entire shunt. Lines 35-48 of column 18 indicate that different therapeutic materials may be used non-uniformly in different regions of the shunt. (See also Tables 1-3 setting forth the distribution of therapeutic agents in proximal and distal portions of the shunt.)

With regard to claims 28 and 30, Tweden discloses that the therapeutic materials may be incorporated in the shunt via various delivery devices and in different amounts in different locations, including a knitted or woven cloth (see column 17, lines 50-60, column 18, lines 35-48).

With regard to claims 17, 31, 49, and 67, applicant's limitations amount to a recitation of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, Tweden specifically discloses that different therapeutic agents may be deployed on different portions of the shunt. Wu specifically discloses that the drug-eluting matrix of the disclosed invention may increase or decrease the release rate of drug from the microparticle, depending on the type of polymer used in the specific microparticle (see column 2, lines 60-67). Therefore, the device suggested by the prior art meets the limitations of the claims.

4. Claims 2, 4, 5, 19, 21, 22, 33, 35, 36, 51, 53, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,928,182 to Kraus in view of US 6,110,155 to Baudino, further in view of US 6,656,506 to Wu et al.

In the specification and figures, Kraus discloses a shunt comprising a conduit with inflow and outflow ends (see FIG 6A) that comprises a valve to control fluid flow and that may be made of silicone or polyurethane in order to enhance biocompatibility (see column 3, lines 15-30, column 6, lines 45-57). Kraus fails to disclose that the shunt

comprises various therapeutic materials or proximal apertures. However, Baudino discloses a shunt (see rejection above) that incorporates therapeutic materials in order to resist inflammation and encapsulation (see Baudino column 3, line 45 to column 4 line 7). Baudino futher discloses the use of proximal apertures 32 to improve fluid flow between the interior and exterior of the shunt (see column 3, lines 20-30). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add the therapeutic materials and apertures disclosed by Baudino to the shunt disclosed by Kraus in order to resist occlusion of the shunt and improve fluid flow, as taught by Baudino.

Kraus and Baudino fail to disclose that the occlusion resistant materials are distributed in agent delivery devices comprising spheres, plugs, seeds, rods, or combinations thereof. Wu discloses an implantable medical device that incorporates polymer-based drug eluting microparticles of various shapes (including spheres) in order to allow site-specific treatment within various portions of the implantable device (see column 2, lines 25-65, column 3, lines 29-31, 39-41, column 4, lines 20-25, 64-67, column 5, lines 10-30). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add drug eluting microspheres as disclosed by Wu to the drug eluting shunt suggested by the prior art, in order to provide site-specific treatment within various portions of the implantable device, as taught by Wu.

5. Claims 8-10, 25-27, 39-41, and 57-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 7,008,397 to Tweden in view of US 6,110,155 to Baudino, in view of US 6,656,506 to Wu et al, further in view of US 2005/0208095 A1 to Hunter et al.

In the specification and figures, Tweden, Baudino, and Wu disclose the device and method substantially as claimed by applicant (see rejection above) with the exception of incorporating mycophenolic acid as a therapeutic agent within the shunt. With regard to claims 8, 9, 25, 26, 39, 40, 57, and 58, Hunter discloses a method of treating patients with various conditions by providing an implantable medical device comprising a therapeutic agent into a patient and allowing the therapeutic agent to elute into the patient (see, generally, paragraph 0014). In an embodiment, the therapeutic material may comprise mycophenolic acid in order to inhibit fibrosis (see paragraph 0223). It has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP 2144.07. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the shunt disclosed by Tweden and Baudino with the therapeutic agent disclosed by Hunter in order to provide the desired therapeutic result, inhibit fibrosis, as taught by Hunter.

With regard to applicant's claims 10, 27,41, and 59, drawn to a "combination" of mycophenolic acid and another agent, applicant fails to specify the amounts of the combination. A mixture of 100% mycophenolic acid and 0% other agents may comprise a combination, giving the term "combination" its broadest reasonable interpretation.

Response to Arguments

6. Applicant's amendment and arguments filed 19 March 2007 have been entered and been fully considered.

7. Applicant's arguments with respect to the pending have been considered but are moot in view of the new ground(s) of rejection, made on the basis of applicant's claim amendments.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

a. US 2007/0071789 A1 Pantelidis et al

i. Implantable medical devices with soluble drug eluting spheres

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie R. Deak
Patent Examiner
Art Unit 3761
9 May 2007